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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/776,010	02/02/2001	Gregory Bruce Wilson	0179/61248-A/JPW/BJA	7419
7590 05/05/2004			EXAMINER	
Cooper & Dunham LLP 1185 Avenue of the Americas New York, NY 10036			LI, BAO Q	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/776,010

**Applicant(s)**

WILSON ET AL.

**Examiner**

Bao Qun Li

**Art Unit**

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 32-40, 42 and 43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 32-40 and 42-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Amendment***

This is a response to the amendment, paper No. 17, filed 12/04/03. Claims 41, 44 and 45 have been canceled. Claims 32, 33, 36, 37, 38, 39, 40, 42 and 43 have been amended. Claims 32-40 and 42-43 are pending before the examiner.

Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

**After reconsidering the claimed invention, new grounds of rejections are requested for the record of the prosecution.**

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 32-40, and 42-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al. (Patent No. 4,816, 563) and Ablashi et al. (Biotherapy, 1996, Vol. 9, pp. 81-86).

3. The claimed invention is drawn to a composition and a method for using the composition to treat chronic fatigue syndrome (CFS) patients, wherein the composition comprises a cell free secretion from a mammary gland secretion or a lyophilized product of the cell-free fluid from an animal infected with human herpesvirus-6A and human Herpesvirus-6B.

1. Ablashi et al. teach a method for treating patients suffering Chronic Fatigue Syndrome (CFS) with antigen specific transfer factor (TF), which is active against EBV, HHV-6 and CMV. The TF is extracted from spleens of BALB/c mice immunized with EBV, CMV, and HHV-6 live virus. Because the transfer factor can produce activity cross the species, injection of the isolated

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TF significantly alleviates the clinical symptom of the patients suffering from chronic fatigue syndrome (CFS) caused by HHV6 infection (see entire document). Ablashi et al. do not teach to use cell free product secreted from a mammal, which contains the antigen specific TF against HSV-6 or HSV-5.

2. Wilson et al. disclose a method for producing an antigen specific excreted transfer factor (TF) isolated from a colostrums or milk of a bovine, and it can be lyophilized and stored dry for later use and/or reconstituted in sterile pyrogen-free water, physiologic saline or any other fluid suitable for injection or oral administration (lines 26 on col. 5 through line 68 on col. 6). Wilson et al. also teach that the antigen specific TF is used for enhance the cellular immunity against specific antigens to which the TF-producing animal is immunized, such as herpes simplex virus, Newcastle's disease, Marek's disease etc.

3. Therefore, it would have been obvious for a person skill in the art at the time the application was filed to be motivated by Ablashi et al and Wilson et al. to use the TF derived from the milk or clostridium product for treating the CFS because the TF derived from a mammal milk product would be much easier and economic to be accepted by patients or market. Hence the claimed invention as a whole is prima facie obvious absence unexpected results.

4. In response to the previous Office Action, Applicants traverse the rejection and submit that Wilson et al. does disclose the HHA-6 transfer factor but does not specify the specific subtypes. While the second reference by Ablashi teaches that 50% of patients suffering CFS treated with the general transfer factor for EBV, HHV-6 and CMV showed some symptomatic relief, Applicants disclose the claimed subject matter showed symptomatic relief in 90% of patients when administering to the CFS patients. Therefore, applicant's claimed subject matter is an unexpected result.

4. Applicant's argument has been fully considered; however, it is not found persuasive because first one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Secondly, the effectiveness of using same product or obviousness of same product from 50% showed by the prior art vs. 90% effective of present application does not mean that the

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composition disclosed by the prior art is patentably different from the claimed composition. Therefore, it cannot be considered as an unexpected result. The rejection maintained.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 32-40 and 42-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Advertisement by Chisolm Biological Laboratory in Positive Health News Report No. 17, Fall Issue 1998, p 29 in view of Advertisement by Chisolm Biological Laboratory in Positive Health News, Fall , 1997, p. 27.

7. HHV6 strains A and B specific transfer factors has been manufactured and sold with the brand name as IMMUNFACTOR6 by Chisolm Biological Laboratory in 1998 (See page 29). The pharmaceutical composition comprising the Transfer Factors is formulated as a simple dried colostrums/whey products in view of the same company's disclosure in the Advertisement by Chisolm Biological Laboratory in Positive Health News, Fall , 1997, p. 27 (See page 27). Therefore, the claimed invention is anticipated by the disclosed prior art.

***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 am to 3:00 pm.

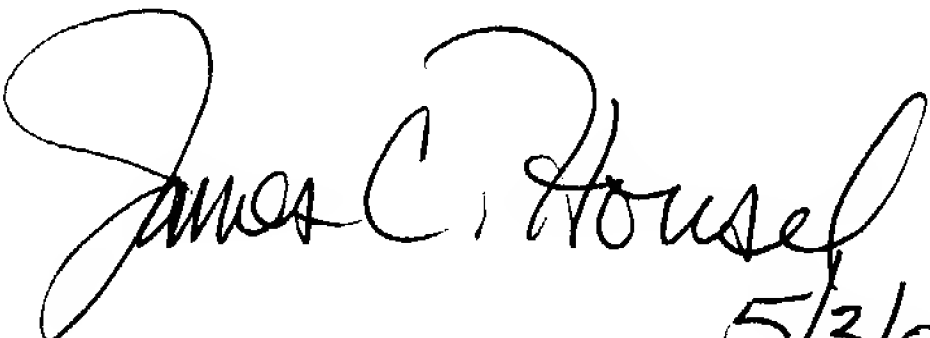
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-272-1600.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bao Qun Li

April 29, 2004

  
JAMES HOUSEL  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1019  
5/3/04